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RD  
05-123  
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Michael ROTHE, Joachim PORZELT, Claude LEHMANN,  
Gunther BECHER, and Stefan DIETZE

Appln. No.: 10/085,390

Filed: February 28, 2002

For: "PROCESS AND APPARATUS FOR THE DETERMINATION OF  
PARAMETERS OF A BREATH CONDENSATE"

Attorney Docket No.: 3648.034

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97 and §1.98

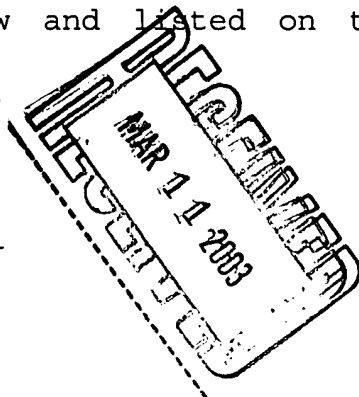
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Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure under 37 C.F.R.  
§1.56, Applicants hereby notify the U.S. Patent and Trademark  
Office of the following documents for the above-identified  
application, which was cited in the International Search Report.  
A copy of the documents set forth below and listed on the  
attached Form PTO-1449 is provided herewith.

1. World Patent No. W0 97/35519
2. German Patent No. DE 199 51 204 A1



The present Information Disclosure Statement is being filed (1) no later than three months from the application's filing date, or (2) before the mailing date of the first Office Action on the merits and, therefore, no Certification Under 37 C.F.R. §1.97(e) or fee under 37 C.F.R. §1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The relevancy of these references is discussed herewith.

**Comments Regarding DE 19951204**

German published application DE 19951204, which was published on May 10, 2001, is directed to a process and device for the analysis of the contents of exhaled breath.

German published application DE 19951204, which was published on May 10, 2001, is directed to a process and device for the analysis of the contents of exhaled breath, wherein breath condensate obtained from the exhaled breath is subjected

to an analysis and the result displayed, the amount of the breath condensate obtained from the exhaled breath is measured and, after a predetermined sample amount is reached, a direct determination of the contained substances by measurement of individual parameters or combined parameters by way of electrochemical sensors is carried out. The amount tested is thereby that portion which is captured in a filter or a storage layer, which is removed from a filter or a storage layer by way of a micro dosing system, which causes a complete filling or ~~saturation of a filter or a storage layer, or which diffuses~~ through a filter or a filter layer. The calibration of the sensors used is carried out during manufacture by providing charge-specific calibration factors for the measurement amplifier or on site by special calibration additives (capsules) or by the use of a reference electrode.

The disclosed device for carrying out this process consists of a collector for breath condensate which can be cooled and which includes a filter or a storage layer for the capturing of the breath condensate, wherein a measurement device for the determination of the amount of the breath condensate and one or more electrochemical sensors for the determination of the contents of the breath condensate are positioned in series downstream of the filter or the storage layer, whereby the

measurement results of the electrochemical sensors are visualized by way of a display. The sensors thereby include a layer which serves as specific substrate for a chemical reaction for specific parameters of the breath condensate or binds specific substances of the breath condensate through immunological or chemical mechanisms. The measurement device preferably consists of a micro dosing system with pump and volume control or a filter or storage layer, the complete filling or saturation of which is the measure for the preselected sample amount, or a microvessel with fill level display. The breath condensate, which is captured by cooling of the exhaled breath to the point of condensation of the aerosol and vapor type components, is collected in the filter or the storage layer 1. The amount of the breath condensate obtained from the exhaled breath is measured and, after reaching a predetermined sample amount 2, a direct determination of the contained substances is carried out by measurement of individual and/or combined parameters by way of electrochemical sensors 3. The temperature is thereby held constant by way of a thermostat device 5 or changed in a defined manner in order to prevent that the measurement results are falsified by decomposition of the sample. The unit use sensor or the electrochemical sensor 3 adapted for repeated measurements is calibrated by a specially

added calibration capsule 4, in that a predetermined calibration impulse is produced on the sensor. It is also possible to carry out the calibration of the sensors 3 at the factory by providing charge specific calibration factors for the measurement amplifier. The measured result is fed directly to an analysis unit 6 which displays the result in a known manner on a display and/or prints it out.


**Difference to Invention of Present Application Serial No.**

**~~10/085,390~~**

The process and apparatus disclosed in DE 199 51 204 only suggests the use of a specially added calibration capsule for the calibration of an electrochemical sensor. It does not in any way disclose a device wherein the preparation of the condensate, if necessary, and the measurement, including calibration, are all carried out in an enclosed cassette, into which the breath condensate is fed. In the device in accordance with the present application, "harmless" electrical measurement results are output by the cassette which can be displayed in a suitable manner, stored or printed out. The cassette as a whole can then be disposed of in the closed condition without danger. Such a device is not disclosed nor even suggested in the German published application.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application, and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

Respectfully submitted,

  
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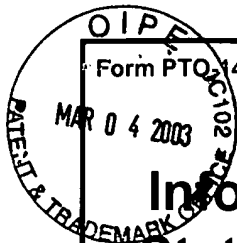
Date: **February 27, 2003**

**CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE**

I hereby certify that a copy of the foregoing INFORMATION DISCLOSURE STATEMENT, Form PTO-1449, and two references thereto for U.S. Application No. 10/085,390 filed February 28, 2002, were deposited in first class U.S. mail, postage prepaid, addressed: Attn: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this the 27th day of February, 2003.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

  
Yate K. Cutliff



Form PTO-1449

# Information Disclosure Statement By Applicant

(use as many sheets as necessary)

Complete if known

Application No:	10/085,390
Filing Date :	February 28, 2002
First Named Inventor:	Michael Rothe et al.
Group Art Unit:	2856
Examiner Name:	
Attorney Docket No.:	PAT 648-2

Sheet 1 of 1

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document No.	Date of Publication MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Patent Document No.	Date of Publication MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T	Check if English Translation is attached.
		WO 97/35519	10-02-1997	Gaston et al.		✓	
		DE 199 51 204	05-10-2001	Rothe et al.			

## OTHER DOCUMENTS


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Examiner Signature:

Date Considered:

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication to applicant.